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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/817,058 | 04/02/2004 | John E. Baker | BA-32448(1) | 2664 |

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| EXAMINER | |
|---|---|
| NOAKES, SUZANNE MARIE | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1653 | |

DATE MAILED: 09/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/817,058 | BAKER ET AL. | |
| | Examiner | Art Unit | |
| | Suzanne M. Noakes, Ph.D. | 1653 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *10 July 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1,3,5-18,24-29,31 and 47-58* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,5-18,24-29,31 and 47-58* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Status of the Application*

1. Upon further consideration, the Finality of the previous Office action dated 10 April 2006, is hereby withdrawn. The request for reconsideration, the petition under 37 C.F.R. 1.47 and the declaration under 37 C.F.R. 1.131 is acknowledged. Jurisdiction for deciding the petition does not reside with the examiner and will be made in due time by the appropriate persons. Claims 1, 3, 5-18, 24-29, 31 and 47-58 are pending.

### *Withdrawal of Objections/Rejections*

2. Any rejection not explicitly recited below is hereby withdrawn.

### *Maintained Objections/Rejections*

### *Claim Rejections - 35 USC § 102(e)*

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claims 1, 3, 5-18, 24-29, 31 and 47-52, 54 are rejected under 35 U.S.C. 102(e) as being anticipated by Brines et al. (US 6,531,121). The details of the rejection can be found in the Office action dated 11 October 2005, pp. 4-8, Section 10; and the previous Office action from 10 April 2006, Section 6.

***Claim Rejections - 35 USC § 102(e)/103***

5. Claims 3-5, 17, 24-26, 28, 53 and 55-58 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Brines et al. (US 6,531,121). The details of the rejection can be found in the previous Office action dated October 11 2005, pp.8-12, Section 11 and the previous Office action from 10 April 2006, Section 7.

***Response to Arguments***

6. Applicant's arguments filed 10 July 2006 have been fully considered but they are not persuasive for the reasons stated below.

7. The Declaration filed on 10 July 2006 under 37 CFR 1.131 has been considered but is ineffective to overcome Brines et al. (US 6,531,121 – Effective Filing Date of 29 December 2000).

8. The evidence submitted is insufficient to establish a conception of the invention prior to the effective date of the Brines et al. reference. While conception is the mental part of the inventive act, it must be capable of proof, such as by demonstrative evidence or by a complete disclosure to another. Conception is more than a vague idea of how to solve a problem. The requisite means themselves and their interaction must also be comprehended. See *Mergenthaler v. Scudder*, 1897 C.D. 724, 81 O.G. 1417 (D.C. Cir. 1897). Applicants have submitted two pages from a laboratory notebook dated 29 May 1998 (Exhibit A) which asserts that "at least in part" these notes establish conception of the claimed invention. However, the disparity between asking the question 'Would

erythropoietin confer late preconditioning?' and what is being claimed, which sets forth a particular treatment protocol which includes obtaining a specific blood serum level within a predetermined amount of time, does not provide sufficient nexus and means to achieve the answer to the question asked. Exhibit G, however, is MWC Discovery Record and Report which establishes proposals, conclusions, and methods to achieve the conclusions thereof which clearly establishes conception that does correlate to the instant claimed invention, however, the report also clearly establishes that the 'Date and Result of the First test of the Discovery' was 19 December 2001.

As stated *supra* the establishment of conception mandates more than a vague question and in the instant case Applicants have not met the burden to establish conception at a date prior to that of Brines et al. and have simply established a date in time for asking a vague, open-ended question with no factual and/or evidentiary means for achieving the answer.

9. The evidence submitted is insufficient to establish diligence from a date prior to the date of reduction to practice of the Brines et al. reference to either a constructive reduction to practice or an actual reduction to practice. Applicants have submitted Exhibits B-F, which are journal articles authored and published by Applicants from 2000-2003., to establish that Dr. Baker and Dr. Shi diligently pursued the invention from the date of conception, 29 May 1998, up to the date of filing on 04 April 2003. However, each and every journal article fails to mention, let alone test of use, erythropoietin for any type of experiment, or in determining the effect of erythropoietin in reducing myocardial ischemia. Thus, Applicants assertion that they diligently pursued a method

for reducing the effects of myocardial ischemia in a patient by administering erythropoietin has little foundation given the evidence to the contrary. In general, proof of actual reduction to practice and diligence requires a showing that the invention actually existed and worked for its intended purpose. The journal articles fail to establish that the claimed invention even existed.

Applicants also submit Exhibits G and H to establish diligence between the time of conception and reduction to practice. Exhibit H is a research proposal dated 2001, and Exhibit G is a Discovery Record and Report which establishes that the "Date and Result of the First Test of the Discovery was 19 December 2001." Thus Applicants in fact are establishing that the first test of the discovery of the claimed invention was *three years, six month and 20 days after conception* and filing was an additional 16 months after that.

MPEP 715.07(a) cleary states: "Where conception occurs prior to the date of the reference, but reduction to practice is afterward, it is not enough merely to allege that applicant or patent owner had been diligent. *Ex parte Hunter*, 1889 C.D. 218, 49 O.G. 733 (Comm'r Pat. 1889). Rather, applicant must show evidence of facts establishing diligence." In the instant case, Applicants have not shown any evidence of diligence which would cover the three years, six month, 20 day time span between conception and the established first date of discovery disclosed in Exhibit G. Thus, there is a lack of reasonable due diligence and the affidavit is ineffective to overcome the art of record.

***New Rejections/Objections***

***Claim Rejections - 35 USC § 102***

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

11. Claims 1, 3, 5-18, 24-29, 31 and 47-58 are rejected under 35 U.S.C. 102(e) as being anticipated by Stamler (US 2004/0009908).

Stamler teaches methods of reducing myocardial oxidative or nitrosative stress caused by either hypoxia or ischemia in patients by administration of erythropoietin (EPO) at a concentration less than 5000 U/kg (see claims 1-73, specifically claims 1-3 and 9-11, and p. 2, paragraph [0009]). The instant claims 1 and 2 recite a method of reducing myocardial ischemia in patient by administering a single dose of EPO in an amount effective to achieve a blood concentration of 0.5-10 U/ml within about 1-35 minutes of administration (claim 1) and dependent claim 2 recites that the dosage is 50-5,000 U/kg. While Stamler concentrates on not increasing the hematocrit levels, rather than the time in which a blood serum level will be achieved post administration, this does not negate the fact that the claims for Stamler and the instant application are claiming the same thing: Administration of the same compound, EPO, in the same concentration, to the same patients suffering from the same myocardial ischemia.

Furthermore, it is irrespective of the cause of the ischemia, e.g. transplant, heart attack, surgery or anything and all things which causes myocardial ischemia (such as those listed in instant claims 13-17 or in claims 21, 28, 35, 49 of Stamler), it is still myocardial ischemia which is being treated which when treated according to the instant claims or by Stamler is going to necessarily and inherently produce the same blood concentration serum levels within 1-35 minutes and this is not going to raise the hematocrit levels. The timing of the administration is addressed by both the instant claims and by Stamler, specifically whether is prior to a myocardial ischemic event, during, at commencement of reperfusion and/or during reperfusion (instant claims), however, Stamler in claims 22-24 also is claiming prior to, at the onset or subsequent to ischemia. Finally, regarding the limitation of a single dose, Stamler teaches/claims that the dose can be a single dose or a continuous dose of EPO to someone suffering myocardial infarction (see claims 40 and 41). A person suffering myocardial infarction will necessarily and inherently suffer from myocardial ischemia (assuming they have survived).

Thus, in all instances and aspects the two sets of claims, although worded slightly differently, inherently claim the same invention. Feit et al. (2003, J. Pat. Trade. Off. Soc., Vol. 85, No. 1, pages 5-21) teach three criteria for inherency. (1) The most important criterion is certainty. Citing *In re Tomlinson* and *In re Zierden*, Feit et al. state that certainty is established when the reference process necessarily **results** in the claimed process as opposed to a **possibility.** (2) The second criterion is chronology; it will always happen. Feit et al. state that the chronological test is forward chronology. Citing *Eli Lilly and Co. v Barr Laboratories, Inc.*, Feit et al. argue that the claimed result

must always be obtained based upon the prior art method. 3) The third criterion is the legal standard. Feit et al., citing *Continental Can,* state that the legal standard is whether the missing descriptive material would be so recognized by a person of ordinary skill in the art as necessarily present in the thing. In the instant case, it will always happen.

***Conclusion***

12. The declaration of record filed under 37 C.F.R. 1.131(b) 05 August 2005 to overcome the previous rejection under Stamler is insufficient to overcome the current rejection because the rejection is made over *claims* of a US Pre-Grant Application of a pending application. MPEP 715.05 clearly states "When the reference in question is a noncommonly owned U.S. patent or patent application publication claiming the same invention as applicant and its publication date is less than 1 year prior to the presentation of claims to that invention in the application being examined, applicant's remedy, if any, must be by way of 37 CFR *>41.202< instead of 37 CFR 1.131. If the reference is claiming the same invention as the application and its publication date is less than 1 year prior to the presentation of claims to that invention in the application, this fact should be noted in the Office action. The reference can then be overcome only by way of interference. See MPEP *> Chapter 2300<."

13. The rejections of record cited in the Final Office action from 10 April 2006 are maintained as the Declaration filed under 37 C.F.R. 1.131 is ineffective to overcome the art of record for the reasons cited above.

14. No claim is allowed.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suzanne M. Noakes, Ph.D. whose telephone number is 571-272-2924. The examiner can normally be reached on Monday to Friday, 7.30am to 4.00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SMN
11 September 2006

JON WEBER
SUPERVISORY PATENT EXAMINER